

that states that "consisting essentially of" restricts the scope of the claimed invention to the specified materials or steps in the claim and to the unspecified materials or steps "that do not materially affect the basic and novel characteristic(s)" of the claimed invention, citing *In re Herz*, 537 F.2d 549, 551-52, 190 U.S.P.Q. 461, 463 (C.C.P.A. 1976). In that particular case, the appellants were attempting to exclude a prior art dispersant in their functional hydraulic fluid by the use of the transitional phrase "consisting essentially of" yet their specification indicated that their composition could contain any well-known additive such as a dispersant. It makes sense that the prior art dispersant could not be excluded from the scope of their claims when the appellants expressly taught that dispersants were an aspect of their invention. In essence, they were contradicting themselves in their claims from what they described in text.

Similarly, the M.P.E.P. relies on the case of *PPG Industries v. Guardian Industries*, 156 F.3d 1355, 1354, 48 U.S.P.Q.2d 1351, 1355 (Fed. Cir. 1998), quoting "PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention." Reading the full case gives a better idea of what the United States Court of Appeals for the Federal Circuit meant by that quote.

In the facts of *PPG Industries*, both PPG and Guardian manufactured green-tinted solar control glass. PPG sued Guardian for infringing PPG's U.S. Patent No. 5,240,886 (the '886 patent) by marketing solar control glass known as Solar Management Glass (SMG). A jury concluded that SMG glass did not fall within the scope of the '886 patent claims. On appeal, the Court of Appeals for the Federal Circuit affirmed.

The '886 patent was directed to a green-tinted glass with specific light transmittance characteristics; and the claims included "consisting essentially of" before a list of ingredients in the base glass composition. Guardian argued that the presence of iron sulfide differentiated SMG glass from PPG's patent since iron sulfide was not listed or identified as an ingredient of PPG's glass composition. The iron sulfide in the tin layer of the SMG glass resulted in a 0.5% change in total light transmittance and a small change in color, measured by a 3 nanometer shift in the dominant wavelength of the light transmitted by the glass. PPG argued that the small changes in the properties of the glass attributable to the iron sulfide in the tin layer did not avoid infringement of the claims of the '886 patent. The jury determined that the unlisted

ingredient of iron sulfide had a material effect on the invention because of jury instructions to find an element has a material effect on the properties of the glass "if the effect is of importance or of consequence to those of ordinary skill in the art of glass making."

The Court of Appeals for the Federal Circuit stated that PPG was entitled to supply its own definition for the terms employed in its patent claim, including the transition phrase "consisting essentially of." The Court further cited its own earlier case of *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 666, 7 USPQ2d 1097, 1102 (Fed. Cir. 1988), in which the Court looked to the prosecution history of a patent to determine whether an unlisted ingredient was excluded from the scope of a "consisting essentially of" claim. It was in this context that the Court then expressed: "PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."

In other words, PPG wanted to include the unlisted ingredient within the scope of their patented claims, which was present in the accused product, in order to win the infringement suit but the transitional phrase "consisting essentially of" functioned to exclude the unlisted ingredient. Basically, the Court of Appeals for the Federal Circuit limited PPG to what they taught in their specification.

Under the present circumstances, the specification and the prosecution history make clear that the unlisted ingredient of interferon, taught as an essential element of the *in ovo* vaccine of Poston *et al.*, is excluded from the scope of the claimed invention.

In conformity with the case law, it is shown that the unspecified element of interferon would have a material affect on the basic and novel properties of Applicant's modified *in ovo* vaccine and method because it would be deemed of importance or of consequence to the ordinary practitioner in the art. Since the interferon of Poston *et al.* is taught as a crucial element to safen the live pathogenic vaccines and overcome the inactivating effects of maternal antibodies, the practitioner would consider the interferon essential. For that reason and reasons of record, "consisting essentially of" operates to exclude interferon from the scope of the present claims.

Furthermore, it is again stressed that nowhere in the instant specification is the inclusion of interferon recommended, promoted, let alone even discussed. It is clear from an overall reading of the specification and the claims that interferon is not contemplated for use with the

present invention. Any person skilled in the art would quickly understand that the invention is not about the co-administration of interferon in any manner whatsoever. In no uncertain terms, interferon is not embraced by Applicant's unique vaccine specially adapted for the *in ovo* method of the claimed invention. The specification and the claims, therefore, give a clear indication that the basic and novel characteristics of the present invention do not include interferon.

In view of the foregoing remarks and the remarks of record, Applicant respectfully asks that the rejections of the pending claims be withdrawn and the application be allowed.

Accordingly, favorable treatment is respectfully urged.

Respectfully submitted,  
WYETH

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